

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

PLANNED PARENTHOOD
SOUTHWEST OHIO REGION, *et al.*,

Plaintiffs,

v.

OHIO ATTORNEY GENERAL
DAVID YOST, *et al.*,

Defendants.

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: Case No. 1:19-cv-00118
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: JUDGE MICHAEL R. BARRETT
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ATTORNEY GENERAL DAVID YOST'S RESPONSE IN OPPOSITION TO
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION [DOC. 4]

Respectfully submitted,

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TABLE OF CONTENTS

| | |
|--|-----------|
| INTRODUCTION..... | 1 |
| FACTS AND BACKGROUND | 3 |
| I. Dismemberment abortion is the most common second-trimester abortion..... | 3 |
| II. Dismemberment of a living fetus is unneeded, as alternative methods can cause fetal demise before dismemberment. | 5 |
| A. Digoxin injection is safe and effective according to many studies..... | 7 |
| B. Potassium chloride injection is also safe and effective | 10 |
| C. Umbilical cord transection is another safe and effective method | 11 |
| III. Ohio enacted a law requiring fetal demise before a dismemberment abortion..... | 11 |
| LAW AND ANALYSIS | 12 |
| I. Plaintiffs must meet a high standard of review in seeking a preliminary injunction in a facial challenge to a law in all applications..... | 13 |
| <p>In seeking a preliminary injunction, Plaintiffs have the burden to demonstrate that they are likely to succeed on the merits, that they are likely to suffer irreparable harm, that the balance of equities tips in their favor, and that an injunction is in the public interest. <i>Winter v. NRDC, Inc.</i>, 555 U.S. 7 (2008). Because they seek facial relief, Plaintiffs must show that, “in a large fraction of the cases in which [the abortion restriction] is relevant, it will operate as a substantial obstacle to a woman’s choice to undergo an abortion.” <i>Cincinnati Woman’s Servs. v. Taft</i>, 468 F.3d 361, 367 (6th Cir. 2006) (emphasis added)</p> | |
| II. Plaintiffs Do Not Show that They Are Likely to Succeed on the Merits..... | 14 |
| <p>Ohio’s fetal demise statute is supported by legitimate state interests, and Plaintiffs have not shown that it creates an undue burden for a large fraction of women seeking second-trimester abortions.</p> | |
| A. Ohio has legitimate state interests that support its fetal-demise statute | 15 |
| <p>Ohio has legitimate interests in promoting respect for life, protecting the integrity of the medical profession, and ensuring unborn children do not needlessly suffer pain. These are important and legitimate</p> | |

interests that warrant deference. *Gonzales v. Carhart*, 550 U.S. 124 (2007); *Women’s Med. Prof’l Corp. v. Taft*, 353 F.3d 436 (6th Cir. 2003). In areas of medical and scientific uncertainty, legislatures have wide discretion. *Gonzales*, 550 U.S. at 163.

B. *Gonzales v. Carhart* provides the appropriate standard by which this Court should consider Ohio’s interests and whether there is an undue burden18

Under *Gonzales*, this Court should consider whether Ohio’s fetal-demise statute (1) imposes an undue burden, and (2) is rationally related to a legitimate state interest. The Supreme Court’s balancing test used in *Whole Woman’s Health v. Hellerstedt*, 136 S.Ct. 2292 (2016), is not applicable here because (1) it did not address the state’s interests in respect or protecting the medical community; (2) it only addressed health-and-safety regulations, which are not at issue here; and (3) *Hellerstedt* did not overrule *Gonzales*, and *Gonzales* is directly on-point, as it ruled upon a similar method regulation based on the same state interests. In determining whether there is an undue burden under an abortion-method regulation, the question is whether there are available and common alternatives that are standard medical options with low complication rates. *Gonzales*, 550 U.S. at 163-66; *Planned Parenthood v. Danforth*, 428 U.S. 52, 79 (1976).

C. There are safe, effective, and common alternatives to live dismemberment abortions.....21

There are three alternatives to live dismemberment abortions—digoxin injections, potassium chloride injections, and umbilical cord transection—all of which are safe, effective, and available. In fact, two of three Plaintiff clinics already provide digoxin injections for second-trimester abortions starting at 18 weeks LMP. The risks associated with these methods do not rise to an undue burden because the risks are not greater than or different from the risks associated with abortion. *Women’s Med.*, 353 F.3d at 447. Furthermore, because the methods are safe, effective, and common, Plaintiffs cannot show that a large fraction of women will be unable to obtain an abortion under Ohio’s fetal-demise law. *Gonzales*, 550 U.S. at 156.

D. Plaintiffs’ contrary arguments fail25

Plaintiffs misstate the law in saying that states cannot ban the most common method of abortion. The relevant question is whether a regulation limits the most common method without an available alternative. *Gonzales*, 550 U.S. 124.

1. Prior case law regarding method regulations do not stand for the proposition that the State must allow the most common abortion method with no limitations26

Plaintiffs' reliance on *Danforth* is unavailing because, there, the state did not identify an available, safe alternative to the method banned in the state's law. Here, there are three safe and available alternatives to live dismemberment abortion. Likewise, neither *Stenberg v. Carhart*, 530 U.S. 914 (2000), nor *Northland Family Planning Clinic, Inc. v. Cox*, 487 F.3d 323 (6th Cir. 2007), considered a proposed alternative to a banned procedure, so they did not consider the central issue in this case. Lastly, *Gonzales* did not enshrine dismemberment abortions as constitutionally untouchable—it only requires an available, safe alternative to any method regulation.

2. Courts analyzing recent dismemberment statutes in other states have applied the incorrect standards.....27

Plaintiffs' reliance on *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310 (11th Cir. 2018); *Whole Woman's Health v. Paxton*, 280 F. Supp. 3d 938 (W.D. Tex. 2017); *Hopkins v. Jegley*, 267 F. Supp. 3d 1024 (E.D. Ark. 2017)—all of which have involved similar fetal-demise statutes—is misplaced because the courts in these cases committed the same error. All three courts failed to apply *Gonzales*'s test for method regulations based on respect for life and protecting the medical community. Rather, the courts incorrectly applied *Hellerstedt*'s balancing tests and looked at the health benefits of the laws compared to their burdens. This was error. Additionally, the Paxton court failed to apply the large-fraction test to plaintiffs' facial challenge. This Court should not follow their flawed analyses.

III. The Remaining Preliminary Injunction Factors Favor the State31

Balancing the potential harm to Plaintiffs against the risk of harm to others and the public interest confirms that Plaintiffs' motion should be denied. Importantly, some of Plaintiff clinics already administer digoxin injections before all abortions beginning at 18 weeks LMP. Plaintiffs have not shown how they will be harmed or how women will be harmed by extending this to all clinics and to all second-trimester abortions. In contrast, keeping the statute quo means that many second-trimester abortions will continue to result in a dismemberment abortion of live, unborn children. The public interest should be against such brutality. Furthermore, injunctions against Ohio's fetal-demise law subjects Ohio to ongoing irreparable harm. *Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers).

IV. Any Injunction Against Ohio’s Fetal-Demise Statute Must Be Limited in Scope.....33

The Supreme Court has held that injunctions should be limited to the problem and courts should “enjoin only the unconstitutional applications of a statute while leaving other applications in force.” *Ayotte v. Planned Parenthood*, 546 U.S. 320, 328 (2006). Here, if this Court believes that some injunction is appropriate (but it is not), it should not enjoin the entire statute. Two of the three Plaintiff clinics use digoxin starting at 18 weeks LMP, and digoxin is a safe, available, and common alternative. Accordingly, to the extent any injunction is warranted (and none is), it should only include dismemberment abortions performed between 15.0 weeks LMP and 17.6 weeks LMP.

CONCLUSION34

CERTIFICATE OF SERVICE35

TABLE OF AUTHORITIES

| Cases | Page(s) |
|--|---------------|
| <i>ACLU Fund of Mich. v. Livingston Cnty.</i> , 796 F.3d 636 (6th Cir. 2015) | 13 |
| <i>Agostini v. Felton</i> , 521 U.S. 203 (1997) | 19 |
| <i>Ayotte v. Planned Parenthood</i> , 546 U.S. 320 (2006) | 3, 33 |
| <i>Berghuis v. Thompson</i> , 560 U.S. 370 (2010) | 30 |
| <i>Cincinnati Women's Servs. v. Taft</i> , 468 F.3d 361 (6th Cir. 2006) | 2, 14 |
| <i>Crawford v. Marion Cnty. Election Bd.</i> , 553 U.S. 181 (2008) | 30 |
| <i>District of Columbia v. Heller</i> , 554 U.S. 570 (2008) | 30 |
| <i>Farnsworth v. Nationstar Mortg., LLC</i> , 569 F. App'x 421 (6th Cir. 2014) | 13 |
| <i>Gonzales v. Carhart</i> , 550 U.S. 124 (2007) | <i>passim</i> |
| <i>Hopkins v. Jegley</i> , 267 F. Supp. 3d 1024 (E.D. Ark. 2017) | 27, 28, 29 |
| <i>Jolivette v. Husted</i> , 694 F.3d 760 (6th Cir. 2012) | 13 |
| <i>In re Judicial Campaign Complaint Against Emrich</i> , 75 Ohio St.3d 1517 (1996) | 24 |
| <i>Maryland v. King</i> , 133 S.Ct. 1 (2012) | 32 |
| <i>Mazurek v. Armstrong</i> , 520 U.S. 968 (1997) | 2, 13 |
| <i>Northland Family Planning Clinic, Inc. v. Cox</i> , 487 F.3d 323 (6th Cir. 2007) | 5, 25, 26 |

| | |
|---|----------------|
| <i>Ohio v. Akron Center for Reproductive Health</i> , 497 U.S. 502 (1990)..... | 14 |
| <i>Planned Parenthood v. Casey</i> , 505 U.S. 833 (1992)..... | 29, 30 |
| <i>Planned Parenthood v. Danforth</i> , 428 U.S. 52 (1976)..... | 20, 25, 26, 27 |
| <i>Rosario v. Rockefeller</i> , 410 U.S. 752 (1973)..... | 30 |
| <i>Stenberg v. Carhart</i> , 530 U.S. 914 (2000)..... | <i>passim</i> |
| <i>Summit Cnty. Democratic Cent. & Exec. Comm. v. Blackwell</i> , 388 F.3d 547 (6th Cir. 2004) | 13 |
| <i>Thomas v. Chi. Park Dist.</i> , 534 U.S. 316 (2002)..... | 30 |
| <i>Tri-Cnty. Wholesale Distribs., Inc. v. The Wine Grp., Inc.</i> , No. 2:10-cv-693, 2010 WL 3522973 (S.D. Ohio Sept. 2, 2010) | 32 |
| <i>United States v. Pretty Prods., Inc.</i> , 780 F. Supp. 1488 (S.D. Ohio 1991) | 26 |
| <i>United States v. Smith</i> , 278 F.3d 605 (6th Cir. 2002) | 26 |
| <i>W. Ala. Women’s Ctr. v. Williamson</i> , 900 F.3d 1310 (11th Cir. 2018) | 17, 27, 28 |
| <i>Whole Woman’s Health v. Hellerstedt</i> , 136 S.Ct. 2292 (2016)..... | 19, 20, 28 |
| <i>Whole Woman’s Health v. Paxton</i> , 280 F. Supp. 3d 938 (W.D. Tex. 2017)..... | 27, 28, 29, 30 |
| <i>Wilkerson v. Utah</i> , 99 U.S. 130 (1878)..... | 1, 16 |
| <i>Winter v. NRDC, Inc.</i> , 555 U.S. 7 (2008)..... | 13 |
| <i>Women’s Med. Prof’l Corp. v. Taft</i> , 353 F.3d 436 (6th Cir. 2003) | <i>passim</i> |

Statutes

| | |
|--------------------------|-------|
| 7 U.S.C. § 1902(a) | 1, 16 |
| R.C. 2307.53 | 12 |

Other Authorities

| | |
|---------------|--------|
| S.B. 145..... | 11, 12 |
|---------------|--------|

INTRODUCTION

This case is about introducing a small amount of humanity to an unquestionably brutal and gruesome procedure that is “laden with the power to devalue human life.”¹ The gruesome procedure—“dismemberment abortion” or “dilation and evacuation” (“D&E”)—consists of tearing an unborn child limb by limb from its mother’s womb. The unborn child typically dies from the dismemberment—that is, the child bleeds to death from being torn apart. So Ohio enacted a law that neither bans abortion nor bans the D&E method, but instead, simply requires a slight modification to that procedure: A doctor must cause “fetal demise” by some other method, such as an injection, before dismembering the unborn child.

This idea—that if life must end, we should retain some humane standards—is well-known in our society, as shown by laws concerning criminals and animals. Indeed, it is remarkable that only now are we extending this concern to unborn life. For centuries, settled law has protected the very worst of our society—murderers—from the pain and indignity of being pulled apart piece by piece.² The concern with needless suffering extends to animals; as over sixty years ago, our Nation adopted, as “the public policy of the United States,” that animals for slaughter could not be cut apart unless they had first been “rendered insensible to pain.”³ Some places have even banned boiling lobsters alive because, “[w]hether we know or don’t know [if they feel pain], it’s our ethical responsibility to give them the benefit of the doubt and not put them into boiling water.”⁴ The state has *at least* as strong an interest in protecting unborn

¹ *Gonzales v. Carhart*, 550 U.S. 124, 158 (2007).

² *Wilkerson v. Utah*, 99 U.S. 130, 135-36 (1878) (holding that it was “safe to affirm that punishments of torture,” such as drawing and quartering, “and all others in the same line of unnecessary cruelty, are forbidden”).

³ 7 U.S.C. § 1902(a).

⁴ Lindsey Bever, *Another Country Bans Boiling Live Lobsters as Scientists Debate Whether They Feel Pain*, Chicago Tribune, Jan. 13, 2018, <http://www.chicagotribune.com/news/nationworld/science/ct-boiling-live-lobster-ban-20180113-story.html>.

children from gruesome deaths as it does in protecting convicted murders, cattle, and lobsters from the same.

Moreover, causing fetal demise as humanely as possible—where a woman’s right to an abortion is not even impinged—builds on current law and practice and is even the choice that almost all women prefer. It builds on current law because both the Supreme Court and the Sixth Circuit have upheld laws that require fetal demise before performing “dilation and extraction” abortions, also known as partial-birth abortions.⁵ It builds on current practice because fetal demise by digoxin injection is now a standard practice for late-term abortions. Indeed, two of the three Plaintiffs use digoxin for *all* abortions at or after 18 weeks in their clinics. And most notably, over 90 percent of women seeking second-trimester abortions *prefer* that fetal demise happens before dismemberment. All Ohio seeks is to require, and move a few weeks earlier, this already common practice. That step does not create significant risks to women, and therefore, does not create an undue burden on women’s access to abortion.

In the face of all this, Plaintiffs seek the “extraordinary and drastic remedy” of a preliminary injunction.⁶ Because they seek facial relief—the complete invalidation of the statute in all circumstances—they must show that the law “will operate as a substantial obstacle to a woman’s choice to undergo an abortion” in a “large fraction” of cases.⁷ Although Plaintiffs insist that the sky will fall if Ohio’s law takes effect, Plaintiffs have not and cannot meet their burden.

First, Ohio’s legitimate and substantial interests justify this law, as Ohio seeks to promote respect for life, protect the medical community, and eliminate the possibility for pain for the unborn child. Second, requiring fetal demise is workable, as shown by Plaintiffs’ admission that

⁵ *Gonzales v. Carhart*, 550 U.S. 124 (2007); *Women’s Med. Prof’l Corp. v. Taft*, 353 F.3d 436 (6th Cir. 2003).

⁶ *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997).

⁷ *Cincinnati Women’s Servs. v. Taft*, 468 F.3d 361, 367 (6th Cir. 2006).

some of them already cause fetal demise before dismemberment or any abortion starting at 18 weeks gestation.⁸ If Plaintiffs already practice fetal demise for some second-trimester abortions, requiring fetal demise cannot create an undue burden in any and all circumstances. Third, there are three available methods— injection of digoxin, injection of potassium chloride, or umbilical cord transection—to cause fetal demise that are safe and effective in causing fetal demise, with single-digit or lower failure rates that affect much less than a “large fraction” of women.

Even if Plaintiffs can overcome all of those hurdles and show a need for some limited injunction, they are not entitled to a complete injunction against the law, especially not as applied to abortions at 18 weeks or later. Some Plaintiffs *admit* that they already use digoxin starting at 18 weeks. Accordingly, the law, by requiring them to do what they already do, cannot possibly impose an undue burden at 18 weeks. Any injunction must be the narrowest possible to address the alleged problem and no broader.⁹

For these reasons, Plaintiffs cannot show that they are entitled to any preliminary injunction against Ohio’s fetal-demise statute, or at least not to an overbroad one. Accordingly, Attorney General Yost respectfully requests that this Court deny Plaintiffs’ motion.

FACTS AND BACKGROUND

I. Dismemberment abortion is the most common second-trimester abortion.

Abortions during the second trimester usually occur by the dilation and evacuation method, commonly called a D&E or dismemberment abortion. *Gonzales v. Carhart*, 550 U.S. 124, 135 (2007); Valley Decl. ¶ 4, Ex. A. A dismemberment abortion requires a clinician to tear apart an unborn child limb by limb. During the abortion, a clinician first dilates a pregnant women’s cervix, a process lasting several hours and often commencing the day before the

⁸ In accordance with Plaintiffs’ motion, references to the age of the fetus are to gestational age, which is measured from the first day of the woman’s last menstrual period (LMP).

⁹ *Ayotte v. Planned Parenthood*, 546 U.S. 320, 328 (2006).

remainder of the procedure. *Gonzales*, 550 U.S. at 135; Valley Decl. ¶ 5. After sufficient dilation, the clinician dismembers the fetus as follows:

The doctor, often guided by ultrasound, inserts grasping forceps through the woman's cervix and into the uterus to grab the fetus. The doctor grips a fetal part with the forceps and pulls it back through the cervix and vagina, continuing to pull even after meeting resistance from the cervix. The friction causes the fetus to tear apart. For example, a leg might be ripped off the fetus as it is pulled through the cervix and out of the woman.

Gonzales, 550 U.S. at 135. Dismemberment and extraction continue piece by piece until the fetus has been completely removed from the uterus. *Id.*; Valley Decl. ¶ 6. During this dismemberment, “the fetus, in many cases, dies just as a human adult or child would: It bleeds to death as it is torn limb from limb.” *Stenberg v. Carhart*, 530 U.S. 914, 959 (2000) (Kennedy, J., dissenting); Valley Decl. ¶ 6. Alternatively, the fetus could die during the dismemberment by the severing of its spinal cord or the crushing of its head. Valley Decl. ¶ 6.

After the clinician has fully dismembered and evacuated the fetus, the clinician “is left with a tray full of [fetal] pieces.” *Stenberg*, 530 U.S. at 959 (Kennedy, J., dissenting). These scattered parts are often reassembled to ensure that no limbs or fetal matter remain in the uterus. Valley Decl. ¶ 6. Finally, the clinician suctions or scrapes the placenta and any remaining fetal parts from the uterus. *Gonzales*, 550 U.S. at 136.

While abortions are generally a safe procedure for the woman, complications can and do occur.¹⁰ These include hemorrhage, infection, cervical laceration, uterine perforation, anesthetic reactions, re-operation for retained pregnancy tissue, and death. Valley Decl. ¶ 7.

¹⁰ Plaintiffs claim that abortions are “markedly safer for women than childbirth,” but that is misleading. True, if one compares the overall mortality rate for abortions to pregnancy, Plaintiffs’ claim has some truth. But most abortions occur in the first trimester, and those abortions have a significantly lower mortality rate. From 1998-2010, the mortality rate for abortions at or less than 8 weeks LMP was .3 for every 100,000 abortions and .5 for abortions between 9-13 weeks LMP. Suzanne Zane et al., *Abortion-Related Mortality in the United States 1998-2010*, 126 *Obstet. Gynecol.* 258, Table 2 (2015), Ex. B-1. This rate increased to a rate of 2.5 for abortions between 14-17 weeks LMP and increased to a rate of 6.7 for abortions at or after 18 weeks LMP. *Id.* During this time, the

According to Plaintiffs, dismemberment abortions in Ohio occur starting at approximately 15 weeks gestation. Doc. 4-3, Rivlin Decl. ¶ 12; doc. 4-4, Martin Decl. ¶ 12. Plaintiff PPSWO performs these abortions until 21 weeks 6 days LMP. Doc. 15, Liner Decl. ¶ 3. Plaintiff PPGOH offers these abortions until 18 weeks 6 days LMP at its Bedford Heights location and until 19 weeks 6 days LMP at its Columbus facility. Doc. 4-3, Rivlin Decl. ¶ 10. Plaintiff Women's Med provides these abortions until 21 weeks 6 days LMP. Doc. 4-4, Martin Decl. ¶ 11. All told, about 12.3 percent of all abortions performed in Ohio occur by dismemberment. Doc. 4-1, Keder Decl. ¶ 15.¹¹

Before 15 weeks LMP, dismemberment of a living fetus is not necessary to complete an abortion. During that time, a clinician can provide surgical abortions by dilating the cervix and suctioning out the fetus. *Northland Family Planning Clinic, Inc. v. Cox*, 487 F.3d 323, 329 (6th Cir. 2007); doc. 4-3; Rivlin Decl. ¶ 11; doc. 4-4, Martin Decl. ¶ 10. And before 10 weeks LMP, clinicians can prescribe medicine that induces termination. *Northland*, 487 F.3d at 329; doc. 4-2, Liner Decl. ¶ 10; doc. 4-3, Rivlin Decl. ¶ 10; doc. 4-4, Martin Decl. ¶ 10.

II. Dismemberment of a living fetus is unneeded, as alternative methods can cause fetal demise before dismemberment.

Second-trimester abortions need not involve the dismemberment of a living being. Indeed, as Plaintiffs concede, clinicians in Ohio can and do perform these abortions *without* dismembering a living fetus. They induce fetal demise before dismemberment. Doc. 4-2, Liner Decl. ¶ 14; Doc. 4-4, Haskell Decl. ¶ 14. Inducing fetal demise is “common and done routinely at clinics across the country,” including in Ohio, Valley Decl. ¶ 8, and “has become widely

mortality rate for pregnancies was 8.8. *Id.* at 5. Thus, while the rate is a bit lower during the late second-trimester, such abortions are not “markedly safer” than pregnancy.

¹¹ Dismemberment abortions account for nearly all the second trimester abortions in Ohio. The other available abortion method post-15 weeks LMP is induction, “where a medication causes the uterus to contract and expel the fetus.” *Northland Family Planning Clinic, Inc. v. Cox*, 487 F.3d 323, 329 (6th Cir. 2007). Because induction involves all the risks and time of full labor and delivery, clinics rarely performed it.

practiced during the past 20 years,” W.M. Hern, *Laminaria, Induced Fetal Demise and Misoprostol in Late Abortion*, 75 Int’l J. Gynecol. Obstet. 279, 280 (2001), Ex. B-2. Indeed, in one study, 50 percent of responding clinicians reported inducing fetal demise before dismemberment. Valley Decl. ¶ 8. And, from at least 2007 through 2010, Planned Parenthood Federation of America required its clinics to perform fetal demise on all abortions starting at 20 week LMP and for abortions at 18 week LMP that met certain criteria. PPFA Policies, Ex. B-17.

Inducing fetal demise before dismemberment carries several benefits. First, patients overwhelmingly prefer it. In one study, 92 percent of patients stated that they preferred to induce fetal demise before extracting the fetus. Valley Decl. ¶ 9. Asked to describe their reasons for this preference, patients reported that they desired “fetal death before the procedure” and believed fetal demise would make the procedure “easier” or “less painful.” Rebecca A. Jackson et al., *Digoxin to Facilitate Late Second-Trimester Abortion: A Randomized, Masked, Placebo-Controlled Trial*, 97 Obstet. Gynecol. 471, 474 (2001), Ex. B-3.

Second, many clinicians also prefer fetal demise to precede dismemberment. Valley Decl. ¶ 10. In one survey, a majority of healthcare professionals stated that fetal demise before dismemberment improved the patients’ experience, as well as the healthcare professionals’ own practices. *Id.* Still other providers prefer to induce fetal demise before dismemberment because it “makes the D&E technically easier with decreased blood loss.” *Id.*

Finally, fetal demise avoids the unintended live birth of a nonviable fetus that nonetheless shows some signs of life. Justin Diedrich & Eleanor Drey, *Induction of Fetal Demise Before Abortion*, 81 Contraception 462, 464 (2010), Ex. B-4. In the second trimester, patients can and do begin labor before or during a D&E procedure. Labor can result in the birth of a nonviable fetus that exhibits some signs of life before dying. Patients and the medical community alike

prefer to avoid this scenario whenever possible. *Id.* By ensuring fetal demise before a dismemberment abortion, patients can avoid giving birth to a nonviable baby who may have signs of life.

Clinicians can cause fetal demise in at least three ways. First, and most commonly, a clinician can inject digoxin. Second, a clinician can administer an intracardiac injection of potassium chloride. Third, a clinician can perform an umbilical cord transection. Each method is safe and effective while ameliorating the brutality of dismemberment abortions.

A. Digoxin injection is safe and effective according to many studies.

Fetal digoxin injections can be carried out transabdominally through the abdomen into the uterus or transvaginally through the vaginal wall or cervix. Clinicians may choose to inject digoxin into the amniotic fluid (intraamniotically) or the fetus (intrafetally). Each of these methods is currently part of the standard practice at PPSWO and Women's Med.¹² At 18 weeks LMP, PPSWO clinicians "attempt to cause fetal demise . . . with an injection of the drug digoxin." Doc. 4-2, Liner Decl. ¶ 14. Clinicians at PPSWO typically inject digoxin transvaginally into the fetus or amniotic fluid. If a transvaginal injection is not possible, clinicians will inject digoxin into the patient's abdomen. Women's Med's practice is similar. There, clinicians inject digoxin starting at 18 weeks LMP either transvaginally into the fetus or transabdominally, if the former method is not possible. Doc. 4-4, Haskell Decl. ¶ 14.

Numerous studies have concluded that digoxin is effective in the vast majority of cases. Michael Molaei et al., *Effectiveness and Safety of Digoxin to Induce Fetal Demise Prior to Second-Trimester Abortion*, 77 Contraception 223, 225 (2008), Ex. B-5; Kristina Tocce et al., *Feasibility, Effectiveness and Safety of Transvaginal Digoxin Administration Prior to Dilation*

¹² PPGOH does not provide digoxin. Doc. 4-3, Rivlin Decl. ¶ 13.

and Evacuation, 88 Contraception 706, 709 (2013), Ex. B-6. In a study of 1,640 cases in which digoxin was administered transvaginally to pregnant women in the second trimester, the digoxin resulted in fetal demise in 99.4 percent of cases. Tocce at 709, Ex. B-6. These results included transvaginal digoxin injections done intraamniotically and intrafetally. The study concluded that second-trimester digoxin injections are “feasible,” “effective,” and “safe.” *Id.* And transabdominal digoxin injections are no less effective. One study found that transabdominal, intrafetal digoxin injections had *zero* failures with a dose of 1.0 mg. Molaei at 225, Ex. B-5. Other studies have documented minimal failure rates that typically hover in the low single digits.

Digoxin injections involve only minimal risk to the patient. Indeed, one study on infection rates and extramural (out-of-hospital) deliveries concluded that the study “add[s] to the growing body of literature that supports the minimal risk inherent in digoxin injection when used as a fetocidal agent.” Rachel Steward et al., *Infection and Extramural Delivery with Use of Digoxin as a Fetocidal Agent*, 85 Contraception 150, 153 (2012), Ex. B-7. That study, which included 4,906 pre-D&E digoxin injections, found just 15 instances of extramural deliveries and two cases of infection, leading the researchers to observe that digoxin “does not cause maternal adverse events in the vast majority of cases.” *Id.* Other studies affirm digoxin’s safety, confirming that the drug does not result in digoxin toxicity, elevated maternal digoxin levels, or altered maternal cardiac rates. Eleanor Drey et al., *Safety of Intra-Amniotic Digoxin Administration Before Late Second-Trimester Abortion by Dilation and Evacuation*, 182 Am. J. Obstet Gynecol 1063, 1066 (2000), Ex. B-8. One study found a less-than-one percent rate of major complications from digoxin injections. Tocce at 710, Ex. B-6. And while some studies have shown an increase in nausea from digoxin injections, even that minor complication is disputed in the medical literature. Valley Decl. ¶ 15.

A digoxin injection is neither a difficult nor time-consuming procedure. One study found that transvaginal digoxin injections averaged just 40 seconds. Aileen M. Gariepy et al., *Transvaginal Administration of Intraamniotic Digoxin Prior to Dilation and Evacuation*, 87 *Contraception* 76, 79 (2012), Ex. B-9. Researchers in another study confirmed that 1 mg digoxin injections added no time to the D&E procedure. Diedrich at 467, Ex. B-4. And most clinicians find the procedure easy or very easy to perform. Gariepy at 79, Ex. B-9. Indeed, providers who have the skill to perform a D&E already have the skillset necessary to perform digoxin injections. Valley Decl. ¶ 14. All obstetric residents learn the ultrasound skills necessary to perform digoxin injections. *Id.* And the injection itself is an extension of the amniocentesis procedure that obstetric practitioners hone during residency. *Id.* In fact, because a digoxin injection is intended to result in fetal demise, clinicians need not use the precision inherent in other obstetric procedures intended to prolong fetal life. *Id.*

Even prominent pro-choice groups recognize digoxin's safety and effectiveness. The National Abortion Federation noted that intraamniotic digoxin was "safe [and] effective," and that, [i]n addition to achieving fetal demise, feticidal agents induce softening of fetal cortical bones and decrease induction-to-abortion intervals if administered 12-24 hours prior to delivery." *See* NAF Policy, Ex. B-18. Likewise, Planned Parenthood Federation of America noted that digoxin was safe to use before second-trimester abortions, that it was "commonly used before abortion to cause fetal demise," that "there are no published reports of serious problems from using digoxin before abortion," that most women prefer to have fetal demise induced, and that "reports from experienced providers claim use of feticidal agents make the procedures easier for the clinician and that it is low risk for the woman." *See* PPFA Policies, Ex. B-17.

B. Potassium chloride injection is also safe and effective

Fetal potassium chloride injections offer an alternative method to cause fetal demise. These injections are not novel—being in use since 1988—and are typically performed to selectively terminate fetuses in multifetal pregnancies. Anna K. Sfakianaki, *Potassium Chloride-Induced Fetal Demise*, 33 J. Ultrasound Med. 337, 338 (2014), Ex. B-10; Valley Decl. ¶ 17. These injections are overwhelmingly successful. In one study of 192 potassium chloride injections, 99.5 percent—all but one injection—successfully induced fetal demise. Sfakianaki at 339, Ex. B-10. The same study confirmed the injection’s safety, with no reported complications for the women. *Id.* Another study concluded that an intracardiac injection of potassium chloride is a “safe and effective” method of fetal demise with no maternal complications. L. Pasquini et al., *Intracardiac Injection of Potassium Chloride as Method for Feticide: Experience from a Single UK Tertiary Centre*, 115 BJOG 528, 530 (2008), Ex. B-11. And the National Abortion Federation noted also that potassium chloride injections were safe and effective. NAF Policy, Ex. B-18. Furthermore, clinicians have safely used potassium chloride injections as early as the late first-trimester for multifetal reductions and fetal anomalies. Juan Vargas & Justin Diedrich, *Second-Trimester Induction of Labor*, 52 Clinical Obstet. Gynecol. 188, 194 (2009), Ex. B-12.

Potassium chloride injections are more complicated than digoxin injections, requiring simultaneous ultrasound guidance and sufficient precision to target and inject the fetal heart or thorax while avoiding the mother’s circulation. But the fetal heart has enlarged enough in the late second trimester to be easily targeted. And early in the second trimester, when the fetal heart is quite small, a clinician need not inject potassium chloride directly into the fetal heart, but may target the larger thorax instead. Valley Decl. ¶ 17; Sareena Singh et al., *Fetal Intracardiac Potassium Chloride Injection to Expedite Second-Trimester Dilation and Evacuation*, 31 Fetal

Diagn. Ther. 63, 64 (2012), Ex. B-13. Plaintiffs do not currently offer potassium chloride injections to induce fetal demise.

C. Umbilical cord transection is another safe and effective method

Finally, clinicians can transect the umbilical cord to induce fetal demise before a dismemberment abortion. This technique has existed since 1972. Kristina Tocce et al., *Umbilical Cord Transection to Induce Fetal Demise Prior to Second-Trimester D&E Abortion*, 88 Contraception 712, 713 (2013), Ex. B-14. A clinician inserts a surgical instrument or suction into the uterus, grasps the umbilical cord, and transects it. The clinician may—but does not need to—use ultrasound guidance to complete the procedure. Fetal demise follows quickly, averaging three and a half minutes in one study, with eleven minutes being the longest time. *Id.* at 714. Like potassium-chloride injections, transection procedures are nearly always effective. In the same large-scale study, fetal demise was achieved in 100 percent of cases before fetal extraction. *Id.* Additionally, the clinic in which the study was conducted has “routinely” performed transection procedures “for all abortions [at or above] 16 weeks.” *Id.* at 713.

Like the other methods, transection procedures are safe for the woman. Patients in the study cited above experienced complications in just 4.9 percent of cases, with one major complication in 407 patients. *Id.* at 714. Patients also did not suffer any ill effects from the three to eleven minute wait between transection and fetal demise. And because fetal extraction takes place during the same appointment as the transection, there is no risk of extramural deliveries. Plaintiffs do not currently offer umbilical cord transection to induce fetal demise.

III. Ohio enacted a law requiring fetal demise before a dismemberment abortion.

Against this factual backdrop, the Ohio General Assembly enacted S.B. 145 (“fetal-demise statute”), which prohibits clinicians from performing a dismemberment abortion

on a living fetus. The bill passed 23-9 in the Ohio Senate and 65-28 in the Ohio House of Representatives on December 13, 2018. Then, Former-Governor John Kasich signed S.B. 145 on December 21, 2018.

Senate Bill 145 states that

[n]o person shall knowingly perform or attempt to perform a dismemberment abortion when the dismemberment abortion is not necessary, in reasonable medical judgment, to preserve the life or physical health of the mother as a result of the mother's life or physical health being endangered by a serious risk of the substantial and irreversible physical impairment of a major bodily function.

A “dismemberment abortion” is defined as follows:

with the purpose of causing the death of an unborn child, to dismember a living unborn child and extract the unborn child one piece at a time from the uterus through use of clamps, grasping forceps, tongs, scissors, or similar instruments that, through the convergence of two rigid levers, slice, crush, or grasp a portion of the unborn child's body to cut or rip it off.

Any clinician who knowingly performs a dismemberment abortion is guilty of dismemberment feticide, which is a fourth-degree felony. Clinicians who perform dismemberment abortions are also subject to civil suits for compensatory and punitive damages. R.C. 2307.53.

LAW AND ANALYSIS

While Plaintiffs acknowledge that fetal demise is all the law requires, they mischaracterize Ohio's fetal-demise statute in a crucial way: they repeatedly say that Ohio *bans* the D&E procedure, the most commonly performed abortion procedure in the second trimester. Doc. 4 at 7 (arguing that the statute's “definition makes clear that it prohibits the dilation and evacuation, or D&E, procedure”). That is false. Ohio's fetal-demise statute does not ban D&E procedures—it bans only D&E procedures performed on a *living fetus*. The statute further clarifies that dismemberment abortion “does not include a procedure performed after the death of the unborn child to extract any remaining parts of the unborn child.” All second-trimester D&Es remain legal so long as the clinician causes fetal demise before dismemberment and extraction.

Because multiple, effective methods exist to achieve fetal demise, Ohio's fetal-demise statute survives constitutional scrutiny.

I. Plaintiffs must meet a high standard of review in seeking a preliminary injunction in a facial challenge to a law in all applications.

"[A] preliminary injunction is an extraordinary and drastic remedy . . . that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). The movant "bears the burden of justifying such relief," and it is "never awarded as of right." *ACLU Fund of Mich. v. Livingston Cnty.*, 796 F.3d 636, 642 (6th Cir. 2015). Indeed, "the proof required is much more stringent than the proof required to survive a summary judgment motion." *Farnsworth v. Nationstar Mortg., LLC*, 569 F. App'x 421, 425 (6th Cir. 2014) (quotation and alternation omitted).

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). As to the first factor, a plaintiff must establish a "strong" likelihood of success, *Jolivette v. Husted*, 694 F.3d 760, 765 (6th Cir. 2012) (quotation omitted); a mere "possib[ility]" of success does not suffice, *Summit Cnty. Democratic Cent. & Exec. Comm. v. Blackwell*, 388 F.3d 547, 551 (6th Cir. 2004). Similarly, the plaintiff must show a likelihood, not just a possibility, of irreparable injury. *Winter*, 555 U.S. at 22. As discussed more fully below, Plaintiffs here fail on all counts.

Additionally, despite Supreme Court guidance that as-applied challenges are preferred to facial challenges in the abortion context, *Gonzales v. Carhart*, 550 U.S. 124, 167-68 (2007), Plaintiffs here seek facial relief. Accordingly, they have an even higher burden. Within the Sixth Circuit, to succeed with a facial challenge to an abortion regulation, the plaintiffs must

show that, “in a *large fraction* of the cases in which [the abortion restriction] is relevant, it will operate as a *substantial* obstacle to a woman’s choice to undergo an abortion.” *Cincinnati Woman’s Servs. v. Taft*, 468 F.3d 361, 367 (6th Cir. 2006) (emphasis added).¹³

Because Plaintiffs seek facial relief, this Court need not—and indeed it would be “undesirable” to—“consider every conceivable situation which might possibly arise in the application” of Ohio’s fetal-demise statute. *Gonzales*, 550 U.S. at 168. “It is neither [the court’s] obligation nor within [its] traditional institutional role to resolve questions of constitutionality with respect to each potential situation that might develop.” *Id.* Thus, Plaintiffs must show more than a list of alleged concerns with causing fetal demise before a dismemberment abortion. They must show that requiring fetal demise will create a “substantial” obstacle to a “large fraction” of women who seek a second-trimester abortion. This is a burden that Plaintiffs have not and cannot meet.

II. Plaintiffs Do Not Show that They Are Likely to Succeed on the Merits

While the Supreme Court has determined that women have the right to terminate their pregnancies, the Court also has determined that this right is not absolute. “[A] state may regulate abortion before viability as long as it does not impose an ‘undue burden’ on a woman’s right to terminate her pregnancy.” *Women’s Med. Prof’l Corp. v. Taft*, 353 F.3d 436, 443 (6th Cir. 2003) (quoting *Planned Parenthood v. Casey*, 505 U.S. 833, 876 (1992)). A regulation creates an undue burden if its “purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.” *Gonzales*, 550 U.S. at 146 (quotation omitted). When analyzing such regulations, courts “are not empowered to ignore or undervalue the governmental interests [the regulation] embodies.” *Women’s Med.*, 353 F.3d at 443. Indeed,

¹³ Those bringing facial challenges should be required to meet the “no set of circumstances” test used by the Court in *Ohio v. Akron Center for Reproductive Health*, 497 U.S. 502, 514 (1990). The Attorney General recognizes that the Sixth Circuit has rejected this but preserves this argument for appeal.

“the fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it.” *Gonzales*, 550 U.S. at 157-58 (quotation and alteration omitted).

Here, Ohio’s fetal-demise statute serves valid state interests and does not create an undue burden on a woman’s right to terminate her pregnancy. Ending the dismemberment of living fetuses is rationally related to Ohio’s interests in promoting respect for life, protecting the integrity of the medical profession, and ensuring that an unborn child does not suffer needless pain. Furthermore, no undue burden results because every woman seeking an abortion will still obtain one, as at least three available procedures are available to cause fetal demise before a dismemberment abortion. These procedures are feasible, safe, and available. In fact, two Plaintiff clinics already use one of the methods for some abortions. Furthermore, as explained below, nothing in prior case law or in the other courts’ decisions related to fetal-demise statutes warrants a finding that Ohio’s fetal-demise statute creates an undue burden.

Because Plaintiffs have not and cannot show that the statute creates a substantial obstacle for obtaining an abortion for a large fraction of women in their second-trimester, Plaintiffs have not met their burden of showing likelihood of success. Accordingly, this Court should deny Plaintiffs’ motion for a preliminary injunction.

A. Ohio has legitimate state interests that support its fetal-demise statute

Ohio’s fetal-demise statute advances legitimate state interests in promoting respect for life, protecting the integrity of the medical profession, and ensuring unborn children do not needlessly suffer pain. In upholding Ohio’s similar partial-birth abortion law—which similarly required fetal demise by banning the procedure *only if* done on a living fetus—the Sixth Circuit noted that “Ohio’s expression of these important and legitimate interests warrants a measure of

deference, rather than [an] assumption of unconstitutionality.” *Women’s Med. Prof’l Corp.*, 353 F.3d at 444. Thus, this Court should not “assume that [the statute] violates the Fourteenth Amendment merely because it reflects interests in preventing unnecessary death and cruelty to partially born children . . . and preserving the integrity of the medical profession.” *Id.*

The Supreme Court has held that a state “may use its voice and its regulatory authority to show its profound respect for the life within the woman,” and that there “can be no doubt” that the state “has an interest in protecting the integrity and ethics of the medical profession.” *Gonzales*, 550 U.S. at 157.

The Supreme Court has noted that dismemberment abortion “is a procedure . . . laden with the power to devalue human life.” *Id.* at 158. Indeed, dismemberment abortion is just as brutal and gruesome as partial-birth abortion. Notably, Justice Ginsburg’s dissent in *Gonzales* objected that the law seemed inconsistent in leaving dismemberment abortion untouched, when it is just as “brutal” and “equally gruesome” as partial-birth abortion, as it involves “tearing a fetus apart and ripping off its limbs.” *Id.* at 182 (Ginsburg, J., dissenting). Justice Stevens likewise described dismemberment abortion as “equally gruesome” as partial-birth abortion. *Stenberg v. Carhart*, 530 U.S. 914, 946-47 (2000) (Stevens, J., concurring).

Indeed, in every context but abortion, we recognize the brutality of dismemberment. Our society does not accept dismemberment as a form of punishment for the worst criminals, *see Wilkerson v. Utah*, 99 U.S. 130, 135-36 (1878) (noting that drawing and quartering is within the prohibition against cruel and unusual punishment), or as a form of slaughter for animals, *see* 7 U.S.C. § 1902(a) (noting that, pursuant to “public policy,” animals may not be “cut” without first being rendered insensible to pain). Even in the abortion context, over 90 percent of women had a “strong preference for fetal demise” when undergoing a dismemberment abortion. Diedrich

at 464, B-4. Certainly then, Ohio has a strong and legitimate interest in showing respect for life by preventing unborn children from being torn limb by limb from the womb.

Additionally, Ohio has an interest in protecting the medical profession. The Court has stressed that the state has a significant role to play in regulating the medical profession. *Gonzales*, 550 U.S. at 157. Dismemberment abortion, like partial-birth abortion, is not only gruesome, but it also can have a profound effect on clinicians and clinic staff. Participating in the procedure has led some to have “anxiety attacks, complete with nausea, palpitations and dizziness”; emotional strain that has affected relationships; and even disturbing dreams.” Valley Decl. ¶ 11. Others who have participated have reported “strong personal reservations” based on the “destructive and violent” nature of the procedure. *Id.* Thus, many providers prefer inducing fetal demise before a dismemberment abortion. *Id.* ¶ 10; *see also* Drey at 1063, B-8. This procedure “might cause the medical profession or society as a whole to become insensitive, even disdainful, to life, including life in the human fetus.” *Stenberg*, 530 U.S. at 961 (Kennedy, J., dissenting). Ohio has an interest in avoiding these harmful consequences to the medical profession and protecting the profession’s integrity and ethics. *Gonzales*, 550 U.S. at 157.

Furthermore, Ohio has an interest in eliminating the unnecessary cruelty and possible pain to the unborn child. *Women’s Med. Prof’l Corp.*, 353 F.3d at 444. With regard to pain, the Attorney General acknowledges the conflicting studies and opinions regarding when an unborn child can feel pain. *See W. Ala. Women’s Ctr. v. Williamson*, 900 F.3d 1310, 1320 n.8 (11th Cir. 2018) (acknowledging the conflict but not deciding the issue because it was not raised by the state). Some say that the perception of pain does not occur until 29 weeks gestation. Diedrich at 464, Ex. B-4. This is asserted, according to those studies, because the systems thought necessary for perceiving pain do not develop until later in the pregnancy. *Id.* However, other

studies have concluded that the fetus can experience pain earlier in its development; and therefore, physicians performing surgery on a fetus provide an analgesia or anesthesia. Valley Decl. ¶ 9. These studies base their conclusions in part on “aversion behavior,” which indicates response “to sensory input.” Sheila Page, *The Neuroanatomy and Physiology of Pain Perception in the Developing Human*, 30 Issues in L. & Med. 227, 232 (2015), Ex. B-15. While there is medical disagreement, by requiring fetal demise, “the issue of whether the fetus could experience pain during the abortion can be circumvented.” Diedrich at 464, Ex. B-4.

Furthermore, the Supreme Court has given “legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty,” particularly when confronted with a facial attack. *Gonzales*, 550 U.S. at 163. In fact, the Court noted that, “in areas fraught with medical and scientific uncertainties, legislative options must be especially broad.” *Id.* (quotation omitted). Indeed, the General Assembly heard testimony regarding fetal pain during committee hearings on S.B. 145, and the possibility of fetal pain was one of the reasons motivating the sponsors of the bill. *See* S.B. 145 Proponent Testimony, Ex. B-19. While the Attorney General acknowledges the uncertainty regarding fetal pain, Ohio had discretion to consider this issue in determining whether to enact the fetal-demise statute.

B. *Gonzales v. Carhart* provides the appropriate standard by which this Court should consider Ohio’s interests and whether there is an undue burden

Gonzales is the most recent case addressing how the undue burden standard applies to laws that regulate a specific method of abortion. It is also the most recent case to address the state’s interests in promoting respect for life and protecting the integrity of the medical profession. Both of these interests are at issue here, and *Gonzales* is directly on-point, so *Gonzales* supplies the necessary framework for evaluating these interests. And under *Gonzales*, a regulation of abortion methods is constitutional if it (1) imposes no undue burden, and (2) is

rationally related to a legitimate state interest, such as the interest in regulating the medical profession and promoting respect for life, including the life of the unborn. 550 U.S. at 158.

It is true that the undue-burden test works a bit differently with respect of health-and-safety regulations. There, the court must balance the law's health interests against the law's burdens as was done in *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292 (2016). The Court in *Hellerstedt* recognized that states have legitimate interests in regulating abortion. 136 S.C. at 2309. But *Hellerstedt* addressed neither the regulation of abortion methods nor the state's interest in respect for life. Rather, *Hellerstedt* dealt with health-and-safety regulations, and the state's sole asserted interest there was the safety of women. *Id.* at 2300, 2309. Thus, the Court held that *when* a state asserts a health interest, it must back up *that* interest on health grounds with health-based evidence.

Outside the health-and-safety context, there is no need to show that an abortion regulation's *health benefits* justify the burdens it imposes. For one thing, it would make little sense to require the states to show a health benefit with respect to laws—like the abortion-method regulations at issue here and in *Gonzales*—unrelated to the state's interest in maternal health. For another, this would require reading *Hellerstedt* as having silently overruled *Gonzales*, which required no such showing. Lower courts must not assume that the Supreme Court has overruled its own precedent. Indeed, even “if a precedent of” the Supreme Court “has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, [lower courts] should follow the case which directly controls, leaving to [the Supreme] Court the prerogative of overruling its own decisions.” *Agostini v. Felton*, 521 U.S. 203, 237 (1997). Here, there is not even any inconsistency between *Gonzales* and ‘some other line of

decisions.” *Moreover*, it would be surprising if *Hellerstedt* had overruled *Gonzales* because Justice Kennedy *joined* the *Hellerstedt* majority and *wrote* the majority opinion in *Gonzales*.

So *Gonzales* controls. And under its framework, the relevant question, as to abortion-method regulations rationally related to a legitimate state interest, is whether the law imposes an undue burden. One way that a law may impose an undue burden is by “subjecting women to significant health risks.” *Id.* at 161 (quotation and alteration omitted); *Stenberg*, 530 U.S. at 931. However, an undue burden does not include “marginal or insignificant risks generalized to the entire population of women seeking late second-trimester abortions.” *Women’s Med. Prof’l Corp.*, 353 F.3d at 447. It also does not include “incidental” effects that make “it more difficult or more expensive to procure an abortion.” *Gonzales*, 550 U.S. at 158 (quotation omitted). Furthermore, medical uncertainty regarding the existence of a significant health risk does not create an undue burden in a facial challenge. *Id.* at 163-64. Indeed, because the *Gonzales* plaintiffs brought a facial attack, the medical uncertainty provided “a sufficient basis to conclude . . . that the Act [did] not impose an undue burden.” *Id.* at 164.

In the context of method regulations, it is particularly important to examine available alternatives. *Planned Parenthood v. Danforth*, 428 U.S. 52, 79 (1976) (invalidating a law that proscribed the most common method of abortion “in light of the . . . unavailability” of an alternative). After all, a regulation of an abortion method cannot be described as imposing an undue burden if it leaves open ample alternative channels for obtaining the procedure. That follows from *Gonzales*, which determined that the partial-birth abortion ban did not subject women to significant health risks because alternatives were available. *Id.* at 163-66. These alternatives were reasonable, commonly used, standard medical options that had low rates of medical complications. *Id.*

Here, like in *Gonzales*, there are available and common alternatives that are standard medical options with low complication rates. Moreover, Plaintiffs also bring a facial challenge to Ohio's law; and therefore, medical uncertainty regarding whether some aspects of those alternatives create a significant health risk does not create an undue burden. Accordingly, Ohio's statute also meets the second prong of the *Gonzales* standard and is thus constitutional.

C. There are safe, effective, and common alternatives to live dismemberment abortions

As described above, there are three alternatives to live dismemberment abortions, all of which are safe, effective, and available. Plaintiffs' response to these three alternatives is that they impose "gratuitous medical risk on women." However, they provide no studies finding any significant risks with the three alternatives and no legitimate reason why they cannot employ at least one of these methods. *See* Pls. PI Motion at 9-11, 17.

Digoxin Injections

Digoxin injections appear to be the most common method of fetal demise for abortions. The use of digoxin has been implemented for well over a decade. *See* PPFA Policies, Ex. B-17 (requiring digoxin use in 2007). And both PPSWO and Women's Med currently use digoxin starting at 18 weeks LMP. *See supra* p. 7. Numerous studies have found digoxin to be feasible, effective, and safe. *See supra* pp. 7-8. And it is neither a difficult nor time-consuming procedure. *See id.* Plaintiffs' objections to this method are two-fold: (1) there are risks of infection, extramural delivery, pain, and emotional difficulty; and (2) it is not always available or effective. Pls. PI Motion at 9. However, neither of these objections represents a substantial obstacle.

The risks associated with digoxin injections—infection, extramural deliveries, and pain—are also associated with all second-trimester abortions; and thus, those risks do not rise to the

level of an undue burden. *Women's Med. Prof'l Corp.*, 353 F.3d at 447. Any claim that these risks are significantly greater than the dismemberment procedure itself is undermined by prominent pro-choice organizations' assertions that digoxin is safe and that "there are no published reports of serious problems from using digoxin before abortion." PPFA Policies, Ex. B-17; NAF Policy, Ex. B-18. While a digoxin injection may increase pain or nausea, these discomforts do not rise to the level of significant health risks. Additionally, Plaintiffs indicate that a woman may experience emotional difficulty with having an injection, but this point is incomplete, as Plaintiffs never discuss the emotional difficulty of learning what a dismemberment abortion entails. "It is self-evident that a mother who comes to regret her choice to abort must struggle with grief more anguished and sorrow more profound when she learns, only after the event, what she once did not know" *Gonzales*, 550 U.S. at 159-60. While *Gonzales* was referring to partial-birth abortion, the same would hold true for dismemberment abortion, as the procedures are equally gruesome.

Plaintiffs' claim that digoxin is not always available to women based on certain health conditions or is not always effective is unavailing. Plaintiffs only assert that "some" women may not be able to have a digoxin injection and that digoxin can fail to cause fetal demise in at most ten percent of cases. Pls. PI Motion at 9; *see also* doc. 4-1, Keder Decl. ¶ 36(saying that medical contraindications are rare); Valley Decl. ¶ 16 (noting that it would be "extremely rare" for a woman of reproductive age to have a contraindication to digoxin). Here, Plaintiffs ignore that it is their burden to prove an undue burden, and that they must show that the regulations create an undue burden in a "large fraction" of cases. Neither "some" nor "ten percent" is a large fraction. While some women may have an as-applied challenge based on a discrete medical issue, Plaintiffs brought a facial challenge instead.

Plaintiffs also claim that digoxin is not used before 18 weeks LMP. Pls. PI Motion at 9. First, this is factually incorrect, as at least one study shows that digoxin can be safely used at 17 weeks LMP. Molaei at 223, Ex. B-5. Second, medical uncertainty over the existence of a significant health risk does not justify facial relief. Nothing shows that use of digoxin between 15 weeks LMP and 16.6 weeks LMP will create significant health risks to the woman that are any different or greater than the risks already associated with dismemberment abortions. *See Valley Decl.* ¶ 13 (noting that there is no difference between a woman or fetus at 15 to 16 weeks versus 17 weeks). Third, the other two fetal-demise methods have been used effectively before 17 weeks LMP and are also safe and available. *Gonzales*, 550 U.S. at 163 (noting that clinicians cannot ignore regulations that require them to “use reasonable alternative procedures”).

Potassium Chloride Injections

Potassium chloride injections offer another avenue for fetal demise. These injections have long been in use to cause fetal demise and are used as early as the first trimester. *See supra* p. 10. They are both safe and effective, as noted by a number of studies and the National Abortion Federation. *See id.* Plaintiffs’ objections to this method are difficulty and its health risks if injected into a woman’s blood stream. Pls. PI Motion at 10. While an injection of potassium chloride into a woman’s blood stream can cause a serious complication, Plaintiffs have identified only one such occurrence. *See* doc. 4-1, Keder Decl. ¶ 39 n.23 (citing G.A. Coke et al., *Maternal Cardiac Arrest Associated with Attempted Fetal Injection of Potassium Chloride*, 13 Int’l J. Obstet. Anesthesia 287 (2004)); Coke at 288, Ex. B-16 (detailing one instance of cardiac arrest complications after a potassium chloride injection, and noting that “[t]here have been no reports hitherto of maternal cardiac arrest or other complications after attempted fetal intracardiac or funic injections of potassium chloride”). Additionally, early in the second

trimester, a clinician can inject the potassium chloride into the thorax, which reduces the difficulty of the procedure. *See* Valley Decl. ¶ 17.

Umbilical Cord Transection

The third method of fetal demise is to transect the umbilical cord. Like the injections, umbilical cord transections are safe and effective. *See supra* p. 11. It also has been available for decades. *See id.* Clinicians currently use transection for abortions at or above 16 weeks LMP. *See id.*

Plaintiffs give three reasons why umbilical cord transection is not possible, all of which are unavailing. First, Plaintiffs identify health risks associated with this procedure, but, as with digoxin, the risks are the same as those for the abortion itself. Pls. PI Motion at 11. Additionally, patients do not suffer any ill effects from the three to eleven minute wait between transection and fetal demise. *See supra* p. 11.

Second, Plaintiffs claim that they could accidentally grasp fetal tissue instead of the umbilical cord, and thereby, violate the statute. This is wrong. In order to violate Ohio's fetal-demise statute, a clinician has to "knowingly perform" a dismemberment abortion. *See* S.B. 145. The "knowing" requirement is not the same as negligence or even recklessness. Indeed, in Ohio, "knowingly" requires that the person is aware that his conduct will *probably* cause a certain result; whereas, "recklessly" describes a situation in which a person ignores a *possible* result. *In re Judicial Campaign Complaint Against Emrich*, 75 Ohio St.3d 1517, 1519 (1996). Here, while it might be possible for a clinician to grasp fetal tissue instead of the umbilical cord, there is nothing to indicate that this is a probable result of the procedure.

Lastly, Plaintiffs assert that it is not always possible to transect the umbilical cord. Pls. PI Motion at 11. This claim contradicts a large study conducted on umbilical cord transections,

which found a 100 percent success rate. *See supra* p. 11. Anyway, that transection might not be possible in “some” cases falls well short of the “large fraction” of cases Plaintiffs must identify.

* * *

Doctors and physicians can be required to “adjust their conduct to the law.” *Gonzales*, 550 U.S. at 156. Thus, while Plaintiffs may not currently practice fetal demise for all dismemberment abortions, there are available, safe, and effective means of achieving this requirement. Plaintiffs must show an undue burden, and they have not done so. They have failed to show that fetal demise before a dismemberment abortion “will prohibit the vast majority of D&E abortions.” *Id.* At most, Plaintiffs can point to a few instances in which a specific procedure may not be effective or available to certain women. But a few instances is not a large fraction. Therefore, Plaintiffs cannot show that they are likely to succeed on their facial challenge to Ohio’s fetal-demise statute.

D. Plaintiffs’ contrary arguments fail

Plaintiffs make the blanket statement that states cannot “ban the most common method of abortion.” Pls. PI Motion at 13. This is wrong. First, Ohio has not banned dismemberment abortions. It has merely added a step—fetal demise—to make the procedure more humane. Second, the correct inquiry is whether a regulation limits the most common method of abortion *without an available alternative*. Thus because there are available alternatives here, Ohio’s fetal-demise statute is more akin to *Gonzales* than *Danforth*, *Stenberg*, or *Northland*.

Plaintiffs’ reliance on recent cases from other districts and circuits related to other states’ fetal-demise statutes is misplaced. As explained below, those cases exhibit the flaw presented throughout Plaintiffs’ motion: they balance the laws’ health interests against their burden notwithstanding the relevance of interests outside the health-and-safety context, and they ignored

plaintiffs’ burden in a facial challenge to show an undue burden on a “large fraction” of women. This Court should not mirror those missteps.

1. Prior case law regarding method regulations do not stand for the proposition that the State must allow the most common abortion method with no limitations

It is true enough that, under Supreme Court precedent, a state cannot “outlaw the most prevalent method of second-trimester abortions” when “there are no ‘safe alternative’ options.” Pls. PI Motion at 13. Thus, the Court in *Danforth* struck down a state law banning the most prevalent procedure because there was no viable alternative at that time. 428 U.S. at 77-78. Indeed, the statute in question arguably banned the proposed alternative. *Id.* at 78. Because the proposed alternative was not in fact available, the only remaining alternatives were hysterotomy and hysterectomy, which were “significantly more dangerous and critical for the woman” than the banned procedure. *Id.* at 76, 79. The Court therefore concluded that, in “light of the present unavailability—as demonstrated by the record—of the [alternative] technique, the outright legislative proscription of saline fails as a reasonable regulation.” *Id.* at 79. *Danforth* does nothing for the Plaintiffs here, where the record demonstrates that there are at least three safe alternative options—including an alternative that is already utilized by two of the Plaintiffs.

Plaintiffs’ reliance on *Stenberg* and *Northland* is similarly misplaced. Neither of these cases considered a proposed alternative to a banned procedure. *See generally Stenberg*, 530 U.S. at 930-46; *Northland Family Planning Clinic, Inc.*, 487 F.3d at 332-40. Because the availability of alternatives is central to this case, *Stenberg* and *Northland* do not provide much, if any, guidance. *See, e.g., United States v. Smith*, 278 F.3d 605, 610-11 (6th Cir. 2002) (holding that prior precedent was “inapposite” because it did not consider an important distinction); *United States v. Pretty Prods., Inc.*, 780 F. Supp. 1488, 1496 (S.D. Ohio 1991) (same). And, to the extent that *Stenberg* considered “theoretical” alternatives (which is a questionable proposition),

see Pls. PI Motion at 17, the alternatives here are not theoretical but are actually used by clinics across the country, including Plaintiff clinics.

Lastly, contrary to Plaintiffs' claim, *Gonzales* did not uphold the federal partial-birth abortion ban because the law preserved the legality of dismemberment abortions. The Court upheld the ban because there were common, low-risk "[a]lternatives" to the "prohibited procedure." *Gonzales*, 550 U.S. at 164. The alternative happened to be dismemberment abortion, but *Gonzales* did not enshrine dismemberment abortions as constitutionally untouchable. For instance, the Court also noted that fetal-demise injections were available as "an alternative under the Act that allows the doctor to perform the procedure." *Id.* The inquiry was the availability of an alternative—not whether clinicians could still perform dismemberment abortions. Because there are available alternatives that are common and have low complication rates, *Gonzales* supports denying Plaintiffs' request for a preliminary injunction.

2. Courts analyzing recent dismemberment statutes in other states have applied the incorrect standards

Plaintiffs correctly note that other federal courts have enjoined fetal-demise statutes similar to Ohio's. See, e.g., *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310 (11th Cir. 2018); *Whole Woman's Health v. Paxton*, 280 F. Supp. 3d 938 (W.D. Tex. 2017); *Hopkins v. Jegley*, 267 F. Supp. 3d 1024 (E.D. Ark. 2017). But each federal case cited by Plaintiffs committed the same error—refusal to apply the appropriate balance set forth in *Gonzales*. Under *Gonzales*, facial challenges to limits on abortion methods fail unless the limits advance no legitimate state interests or impose an undue burden on a woman's right to an abortion by posing significant health risks. See *supra* pp. 18-21; *Gonzales*, 550 U.S. at 146; *Stenberg*, 530 U.S. at 931; *Danforth*, 428 U.S. at 79. When medical uncertainty on significant health risks exists, states may nonetheless regulate procedures, and *Gonzales* instructs that a facial challenge cannot

succeed. 550 U.S. at 163. Each district court to enjoin a fetal-demise statute has run afoul of some part of this standard.

In *Williamson*, the Eleventh Circuit affirmed the entry of a permanent injunction against Alabama’s fetal-demise statute. 900 F.3d at 1330. The court recognized medical uncertainty concerning whether the law imposed significant health risks. Under *Gonzales*, states may constitutionally resolve medical uncertainty in favor of method limitations, 550 U.S. at 163, but the *Williamson* court refused to apply that decision. The court concluded that *Gonzales*’s instruction to defer to states when medical uncertainty exists is appropriate only for *facial* challenges. *Williamson*, 900 F.3d at 1330. The plaintiffs, according to the court, had asserted an as-applied challenge. Thus, the district court—not the legislature—could resolve questions of medical uncertainty. In reviewing the district court’s fact finding, the appellate court was “not left with a definite and firm conviction that a mistake has been committed in any of the [district] court’s material findings” on the statute’s significant health risks. *Id.* (quotation omitted).

Here, unlike *Williamson*, Plaintiffs have asserted a facial challenge to Ohio’s law. Accordingly, no justification exists for departing from the rule of *Gonzales* that medical uncertainty “does not foreclose the exercise of legislative power in the abortion context,” and in fact, “provides a sufficient basis to conclude in this facial attack that the Act does not impose an undue burden.” 550 U.S. at 164.

Paxton and *Jegley*, meanwhile, strayed from *Gonzales*’s framework in another way. They wrongly imported an additional requirement believing that, under *Hellerstedt*, fetal-demise laws must somehow benefit women’s health and that those health benefits must outweigh the burdens. In *Paxton*, the district court very explicitly concluded that Texas’s fetal demise statute “fails to ‘confer[] benefits sufficient to justify the burdens upon access [to abortion] that [the

Act] imposes.” 280 F. Supp. 3d at 953 (quoting *Hellerstedt*, 136 S. Ct. at 2299). Similarly, in *Jegley*, the court held that it must “weigh[] the asserted benefits against the burdens” imposed by Arkansas’s fetal-demise statute. 267 F. Supp. 3d at 1055 (quoting *Hellerstedt*, 136 S. Ct. at 2310). However, in its application, the court only considered the health benefits and burdens and did not discuss the state’s legitimate interests in promoting respect for life and protecting the medical community. *Id.* at 1055-64. But unless the law is a health-and-safety regulation, *Gonzales* controls, and under *Gonzales*, the appropriate analysis does not include balancing the health benefits of a law with its burden. *See supra* pp. 18-21.

The district court in *Paxton* also committed additional errors by not applying the “large fraction” analysis and by holding that the requirement of an additional step before an abortion “in and of itself” was an undue burden. 280 F. Supp. 3d at 948. As to the “large fraction” analysis, the court correctly noted that this was the standard, *id.* at 952, but its conclusions show that it did not apply this test. For example, the court found that “digoxin injections *are not always reliable*,” that digoxin was “not a feasible method of, *in all instances*, inducing fetal demise,” and that none of the proposed methods were “feasible . . . *in all instances*.” *Id.* at 949, 950, 952 (emphasis added). The “large fraction” standard means that the regulation must impose an undue burden on a significant number of women. A regulation is not facially invalid merely because it could create an undue burden for some women—that is the purpose of an as-applied challenge. The court’s requirement that the alternatives be successful “in all instances” is not the appropriate standard.

Furthermore, “adding an additional step” to the abortion process does not “in and of itself” demonstrate that the “state has erected an undue burden.” *Id.* at 948. If the state is not allowed to add additional steps, then even the Supreme Court’s decision in *Casey* was wrongly

decided because it upheld the prior steps of a 24-hour waiting period after informed consent and a parental consent provision. 505 U.S. at 881-87, 899-900. This pronouncement also would elevate abortion rights above even enumerated constitutional rights in which additional steps may be added to the process. *See Crawford v. Marion Cnty. Election Bd.*, 553 U.S. 181 (2008) (upholding a requirement to present photo identification before exercising one’s right to vote); *District of Columbia v. Heller*, 554 U.S. 570, 626-27 (2008) (noting that its opinion should not cast doubt on “laws imposing conditions and qualifications on the commercial sale of [fire]arms,” even though the Second Amendment protected a person’s right to own a firearm); *Thomas v. Chi. Park Dist.*, 534 U.S. 316 (2002) (upholding a permit requirement for conducting a large-scale event at a public park in the face of a First Amendment challenge); *Rosario v. Rockefeller*, 410 U.S. 752 (1973) (upholding a requirement that voters must register under their party of choice months before the primary election); *cf. Berghuis v. Thompkins*, 560 U.S. 370 (2010) (requiring a person to affirmatively state that he is invoking his right to remain silent before police must cut off questioning). Both *Casey* and decisions about other rights show that requiring an additional step before people can exercise their constitutional rights does not “in and of itself” demonstrate that the regulation violates the Constitution. The *Paxton* court’s conclusion to the contrary was error.

Because none of the decisions cited by Plaintiffs applied the appropriate framework for a facial challenge to a method regulation and because they contained other errors, this Court should not follow their analyses. Rather, as fully detailed above, this Court should apply *Gonzales* and find that because the law does not impose a substantial obstacle to abortion for a “large fraction” of women, it does not impose an undue burden warranting facial relief.

III. The Remaining Preliminary Injunction Factors Favor the State

Balancing the potential harm to Plaintiffs against the risk of harm to others and the public interest confirms that Plaintiffs’ motion should be denied.

Plaintiffs claim that their clinicians will stop performing any second-trimester abortions absent an injunction, thereby causing irreparable harm to them and their patients. Doc. 4 at 12. Surely threats from abortion providers that they will quit cannot be the appropriate inquiry; otherwise, they could bypass the analysis by always claiming that they will quit. Rather, the courts have held that physicians do not have unfettered discretion in the abortion context. *Women’s Med. Prof’l Corp.*, 353 F.3d at 447 (noting that “by no means must a State grant physicians unfettered discretion in their selection of abortion methods” (quotation omitted)).

Furthermore, Plaintiffs’ claim rings hollow. At 18 weeks LMP and thereafter, Plaintiffs’ clinicians already do exactly what Ohio’s fetal-demise statute requires them to do—cause fetal demise through a digoxin injection. Doc. 4-2, Liner Decl. ¶ 15; doc. 4-4, Haskell Decl. ¶ 14. Requiring Plaintiffs’ clinicians to do what they already do is not a source of irreparable harm. In addition to digoxin injections, Plaintiffs’ clinicians have the option of performing an intrathoracic potassium chloride injection¹⁴ or an umbilical cord transection. According to the relevant literature, these methods are safe, effective, available throughout the second trimester, and easily performed by clinicians with experience in performing second-trimester abortions. *See supra* pp. 7-11; Valley Decl. ¶ 17. Plaintiffs’ clinicians’ professed unwillingness to use these alternative procedures does not establish irreparable harm. Clinicians “are not entitled to ignore regulations that direct them to use reasonable alternative procedures.” *Gonzales*, 550 U.S.

¹⁴ Intracardial potassium chloride injections are typically only performed in the late second trimester, when Plaintiffs’ clinicians use digoxin to induce fetal demise.

at 163. At most, Plaintiffs and their clinicians would suffer the self-inflicted harm of refusing to perform reasonable, safe, and effective alternative procedures absent an injunction.

In contrast, an injunction would upend the shared interests of the public and the state in honoring both life and law. Through their elected representatives, the citizens of Ohio have concluded that requiring fetal demise before dismemberment abortions advances their interests in honoring life, protecting the medical profession, and avoiding fetal pain. By continuing to countenance the live dismemberment of unborn children, the medical profession and even society as a whole risks becoming “insensitive, even disdainful, to life.” *Stenberg*, 530 U.S. at 961 (Kennedy, J., dissenting). Ohio’s fetal-demise statute promotes the public’s respect for the sanctity of life, even unborn life. Further, by quickly ending fetal life before dismemberment, the statute also promotes the public’s interest in avoiding the possibility of fetal pain. The entry of an injunction would extinguish these interests.

Additionally, an injunction would subject the State to ongoing irreparable harm. As various Supreme Court justices have recognized, “[a]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.” *Maryland v. King*, 133 S.Ct. 1, 3 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, C.J., in chambers)). So, too, does the public have an interest in the validity and enforceability of its duly enacted laws. *Tri-Cnty. Wholesale Distribs., Inc. v. The Wine Grp., Inc.*, No. 2:10-cv-693, 2010 WL 3522973, at *8 (S.D. Ohio Sept. 2, 2010).

Against these interests, Plaintiffs can interpose only (1) their self-inflicted unwillingness to perform certain safe and effective procedures and (2) their desire to maintain the status quo. The brutal status quo is not worth maintaining in light of the State’s and the public’s interest in

honoring life, protecting the medical profession's integrity, avoiding fetal pain, and enforcing Ohio laws. The balance of interests thus favors the denial of Plaintiffs' motion.

IV. Any Injunction Against Ohio's Fetal-Demise Statute Must Be Limited in Scope

As detailed above, Plaintiffs have not and cannot show that Ohio's fetal-demise statute imposes a substantial obstacle for a large fraction of women seeking second-trimester abortions. *See supra* pp. 21-30. Rather, even at this initial stage, the record definitively shows the opposite. Indeed, the evidence shows that digoxin injections—a common, simple, safe procedure—will cause fetal demise somewhere between 90 to 99 percent of the time. *See supra* pp. 7-8. Thus, Plaintiffs should not receive large-fraction, facial relief for what are speculative concerns about narrow, as-applied scenarios. And they certainly should not receive such broad, imprecise relief before *any* enforcement of the law has occurred. *Gonzales*, 550 U.S. at 167-68.

Because Plaintiffs fail to meet the burden for their requested relief, they are not entitled to a preliminary injunction against the statute. However, to the extent this Court is inclined to grant a preliminary injunction, it must be far narrower in scope. The Court must “limit the solution to the problem.” *Ayotte v. Planned Parenthood*, 546 U.S. 320, 328 (2006). In this vein, courts should “enjoin only the unconstitutional applications of a statute while leaving other applications in force.” *Id.* at 329.

Here, even if the Court finds that some applications are likely to cause an undue burden, it should not enjoin the entire statute. Two of the three Plaintiff clinics admit that they use digoxin starting at 18 weeks LMP. The record shows that digoxin is a safe, available, and common alternative at this stage of the woman's pregnancy. And while PPGOH clinicians do not use digoxin, their reluctance to use a common and safe alternative does not mean that the statute creates an undue burden. Furthermore, to the extent that a digoxin injection fails, this Court can craft a remedy for those limited circumstances.

Accordingly, to the extent any injunction is warranted (and none is), it should only include dismemberment abortions performed between 15.0 weeks LMP and 17.6 weeks LMP.

CONCLUSION

For these reasons, Attorney General Yost respectfully asks this Court to deny Plaintiffs' motion for a preliminary injunction, or in the alternative, only grant as-applied relief for abortions performed between 15.0 week LMP and 17.6 weeks LMP.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing was electronically filed with the U.S. District Court, Southern District of Ohio, on March 5, 2019, and served upon all parties of record via the court's electronic filing system.

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